

It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

A **vaccine complication** in Florida highlights the importance of distributing the most recent VIS to your patients. In 1997, a 3-month-old boy developed vaccine-associated paralytic poliomyelitis (VAPP) following a first dose of OPV. The boy's parents reported that their physician furnished them with the 1994 polio VIS at the time of vaccination. The polio VIS had been revised in 1997 to reflect the ACIP preference for sequential use of inactivated polio vaccine (IPV) followed by live polio vaccine (OPV), making the 1994 polio statement that was given to the parent outdated. **Note:** the most current polio VIS carries the date of 1/1/00.

This article was originally written by Neal A. Halsey, MD, Director, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health and was updated by the Immunization Action Coalition in October 2005.

This article was further modified for the AIM Provider Tool Kit.

The risks of serious consequences following vaccines are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications such as the one in the Florida case are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccinees (or the parents/legal guardians of minors) with objective information on vaccine safety and the diseases that the vaccines protect against so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in health care providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

"We have an obligation to provide patients and/or parents with information that includes both the benefits and the risks of vaccines. This can be done with the Vaccine Information Statements that health care providers are required by law to provide prior to the administration of vaccines."

Walter A. Orenstein, MD, Past Director
National Immunization Program, CDC

What are VISs?

VISs are developed by the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccinee or the minor child's parent or legal representative about the risks and benefits of each vaccine. The VISs are not meant to replace interactions with healthcare providers who should answer questions and address concerns that the vaccinee or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing influenza, diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, hepatitis A, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), or pneumococcal conjugate vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult vaccinee or to the child's parent/legal representative.

VISs are also available for pneumococcal polysaccharide, meningococcal, yellow fever, rabies, anthrax, and typhoid vaccines, and their use is recommended but not required by federal law. (EDITOR'S NOTE: Use of the meningococcal VIS will become mandatory in 2006. This vaccines will soon be covered by the NCVIA.)

State or local health departments or individual providers may place identifiers on the VISs but any other changes must be approved by the Director of CDC's National Immunization Program.

What to do with VISs

Some of the legal requirements concerning the use of VISs are as follows:

1. Before an NCVIA-covered vaccine is administered to anyone (this includes adults!), you must give the patient or the parent/legal representative a copy of the most current VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine.
2. You must record in your patient's chart the date the VIS was given.
3. You must also record on the patient's chart the publication date of the VIS, a date which appears on the bottom of the VIS. The most current VIS must be used.

Most current versions of VISs

DTaP/DT/DTP.....7/30/01	MMR.....1/15/03
Hepatitis B.....7/11/01	Varicella.....12/16/98
Hepatitis A.....08/04/04	Hib.....12/16/98
Meningococcal....10/07/05	Polio.....1/1/00
Influenza (TIV).....10/20/05	Td.....6/10/94
Influenza (LAIV)...10/20/05	Tdap.....09/22/05
Yellow fever.....11/09/04	Rabies.....11/4/03
Japanese Encephalitis.....05/11/05	Typhoid.....05/19/04
Pneumococcal polysaccharide (PPV23)....7/29/97	
Pneumococcal conjugate (PCV7).....9/30/02	

How to get VISs

VISs are available from your local health department. In Michigan, it is important to use the Michigan versions of VISs because they include information about the Michigan Childhood Immunization Registry (MCIR). By state law in Michigan, parents must be informed about MCIR. VISs that are obtained from other sources (e.g., from the CDC or IAC websites) do not contain information about MCIR.

Foreign language versions of VISs (which include information about MCIR) are available in 33 languages. To receive VISs in foreign languages, call the Michigan Department of Community Health at 517-335-8159. "

To obtain a complete set of current VISs, call your local health department.